PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/677,716	Confirmation No.: 9204
Applicant :	Amr Salhieh	
Filed :	October 2, 2003	
TC/A.U. :	3773	
Examiner :	Tyson, Melanie Ruano	
Title :	Expandable retrieval device	
Docket No. :	1001.1633101	
Customer No. :	28075	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

CERTIFICATE FOR ELECTRONIC TRANSMISSION: The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 20 day of January, 2010.

By Jill Standish
Jill Standish

Dear Sir:

Appellants have carefully reviewed the Final Office Action of September 21, 2009 and the Advisory Action of December 1, 2009. Currently, claims 1, 2, 4-12, 14-16, 18-26, 28, and 29 are pending in the application and have been rejected by the Examiner. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 1, 2, 4-12, 14-16, 18-26, 28, and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. (U.S. Patent Application Publication No. 2003/0004537), hereinafter Boyle, in view of Dubrul et al. (U.S. Patent No. 6,221,006), hereinafter Dubrul. Appellants respectfully traverse the rejection for at least the reasons that all elements of these claims are not disclosed in this combination of references. As such, these claims are believed to be allowable over these references.

The final rejections of independent claims 1, 15, and 29 were based upon the disclosure of Boyle as it relates to Figure 12 as described at paragraph [0060]. In that embodiment, the sheath 112 has a distal tip portion 114. The tip 114 is said to be bonded to portion 118 which forms the remainder of sheath 112. Accordingly, Boyle appears to teach, in the embodiment of cited Figs. 12 and 13 as well as others, a uniform diameter device in which portions 118 and 114 of sheath 112 are of the same diameter and in which the illustrated portion 118 forms the remainder of sheath 112 without a disclosed variation in diameter.

In the Advisory Action, the Examiner appears to rely upon a different embodiment, that of Fig. 1, which has an "expandable housing" which does not appear to expand in that embodiment, but no ring member 116 which might correspond to a "braided member including a plurality of filaments and defining a radially expandable inner lumen configured to receive and encapsulate the intravascular device therein" as recited in independent claims 1, 15, and 29 with some variation in the language employed. As will be seen in Fig. 2, the lumen of the sheath of Figs. 1-3 appears to be large enough to accommodate the filter or stent without any radial expansion. In essence, the sheath of Figs. 1-3 is pre-expanded and does not appear to comprise "a radially expandable inner lumen configured to receive and encapsulate the intravascular device therein". The Examiner has also made reference to the embodiment found in Fig. 1 of Boyle with the assertion that portion 22 of that device may be considered the proximal end of the elongated shaft corresponding to portion 118 of the embodiment of Fig. 12. This assertion does not appear to be supported by the disclosure. The proximal end of Fig. 1 which most nearly corresponds to the proximal end of the elongated shaft of the claims appears to be identified by reference numeral 40 which is identified by Boyle as proximal end 40. Further, the embodiment of Fig. 1-3 does not appear to have a differentiated tip region 114 corresponding to that of Fig. 12 which is both highly elastic and biased by ring member 116 to contract the tip "once the tip extends over the component to be restrained". The sheaths of Fig. 1 and 12 are fundamentally different in form and function.

As noted earlier, the overall configuration of the embodiment of Fig. 1-3 is characterized as a rapid exchange-type sheath, while the sheath of Fig. 12 is a full length-type sheath with different requirements regarding column stiffness for pushability. In the Advisory Action, the Examiner introduces the paragraph [0019] description of the sheath of Figs. 4 and 5, which sheath comprises "a relatively stiff tubular material which has interspersed therein elastic material to allow the housing portion to expand and contract" in an effort to provide a flared distal section missing in the previously relied upon embodiment of Fig 12 which contains the element 116 which the Examiner proposes to replace with a braid of Dubrul.

Those embodiments of Boyle which have a flared distal section appear to be fabricated from a relatively stiff tubular material and appear to have an initially enlarged diameter and thus have no apparent need for addition axial stiffness or even significant radial expansion. In characterizing paragraph [0019] in the Advisory Action, the Examiner appears to have misread and/or mis-combined the teachings of that paragraph, which do not appear to apply to the embodiment of Fig. 12 used in the final rejection to which Appellants responded. Paragraph [0019], which appears to relate to the embodiments of Figs. 4-5 as well as the uniform diameter, non-flared embodiment of Figs. 6-7 rather than to either the embodiment of Figs. 1-3 discussed in the Advisory Action or the embodiment of Fig. 12 cited in the Final Office Action, appears to admit of an embodiment in which a stiff tubular member provides axial stiffness (lines 1-9) or an embodiment in which the housing is formed from a highly elastic tubular member with included axial reinforcing members (lines 12-18). Again, it must be emphasized that none of the embodiments of Figs. 1-7 appear to have a member 116 encased in an elastic jacket 114 which might be replaced by the braid of Dubrul as proposed by the Examiner and the function of the contractile ring of Fig. 12 is not a function provided by the radially expanding braid of Dubrul.

Continuing with the discussion of the Advisory action, the Examiner appears to have mischaracterized the portion of the response dealing with the teaching of Boyle as well as the assertion that Boyle would become "inoperable" under the proposed modification. Boyle, in the embodiments of Figs. 1-5 and even 6-7, appears to teach that at least the distal portions of the devices are axially stiff due to the materials used in their construction and thus it would appear that a modification which relies upon a significant axial compression, such as the braid of Dubrul, would be ineffective simply because the section would be largely incompressible and thus would not expand significantly. Appellants did not use the word "inoperable" and that would not appear to be a proper argument; however it does appear to be the case that one of ordinary skill in the art would not be motivated to incorporate an braid of Dubrul, which relies for its utility upon axial compression of the braid, into a sheath of Boyle which is largely axially incompressible for the reason that there would be little if any expectation of success.

In the Advisory Action the Examiner attempts alter the term "yarn" as used by Dubrul to denote "individual non-elastic filaments" (col. 14, lines45-46) to include the claimed "wherein said plurality of filaments comprise multi-filar threads" which indicates that the filaments are multi-filar as opposed to the individual filaments of Dubrul's yarn.

Lastly, the Examiner asserts that a claimed structural feature, the extension of the proximal portion of the braided member "proximally of a distal end of the elongated shaft member and coupled to the distal section of the elongated shaft member and the distal portion of the braided member extending distally of the distal end of the elongated shaft member" as mere "making integral". Instead, extending the braid across the boundary imparts mechanical properties to the more proximal portion which would not otherwise be present.

With respect to the unaddressed arguments presented after the Final Office Action and earlier, the ring 116 of Boyle is said to function in the manner described in paragraph [0058]:

> "In use, the coil spring 94 is normally biased to the smaller collapsed diameter C, as shown in FIG. 8. Thereafter, when a outward radial force is applied to the inner surface 96 of the housing portion 90, the coil spring expands outwardly allowing the housing portion to expand as needed to capture the filter basket."

Accordingly, the ring appears to respond to an outward radial expansion force and not to an axial one. This interpretation is further supported by an examination of Figs. 12 and 13 of Boyle in which the axial dimension of the elastic tip 114 remains unchanged upon expansion confirming that the expansion is not a response to axial compression. It would appear that if the ring 116 of Boyle were to be replaced by a braid of Dubrul, there would be no radial expansion during introduction of a filter or other medical device for the reason that the braid would not appear to be subjected to significant compressive axial forces. Were such axial forces present and significant, it would appear that the tip portion, which is said to be even more elastic than the adjacent portion 118, would be prone to undesirable compressive bucking. The modifications suggested by the Examiner would appear to impermissibly alter the operating principles of Boyle by requiring that the device become responsive to an axially applied force, which does not appear to be present, rather than to a radially outward applied force. (MPEP 2143.01, VI.)

Boyle in view of Dubrul does not appear to provide all elements of the independent claims 1, 15, and 29. There appears to be no flared distal section in an embodiment which includes a tip with an element which might reasonably be replaced by the braid of Dubrul or indeed any embodiment of Boyle which appears to be radially expansive in response to an axial force. The only forces to which Boyle appears to be responsive are radial outward forces. The filter of Boyle does not appear to have a proximal support hoop which forms a proximally facing opening nor is the proximally facing opening "within at least a portion of the radially expandable inner lumen of the braided member". To the extent that a braid of Dubrul might replace the ring 116 of Boyle, it would appear to be located well distal of the distal end of the elongated shaft member identified as corresponding to shaft 118 of Boyle. The braids of Dubrul which have the property required by the proposed substitution appear to be interwoven braids rather than including plurality of filaments arranged in two sets of parallel helices wound in opposite directions about a common longitudinal axis. The remaining claims depend from these nonobvious independent claims and thus are believed to be nonobvious as well

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: Jan, 19, 2010

Glenn M. Seager, Reg. No. 36,926
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Tel: (612) 677-9050